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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/070,732	04/04/2002	Viktoria Petrovna Yamskova	P67704US0	9698

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EXAMINER	
TELLER, ROY R	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 08/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/070,732	YAMSKOVA ET AL.	
	Examiner	Art Unit	
	Roy Teller	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 May 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9* is/are pending in the application.

4a) Of the above claim(s) *7-9* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *0704*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This office action is in response to the election, received 5/24/04, in which applicant elected the compound of the glycoprotein covered by claim 4, without traverse. The claims readable on the elected species are claims 4, 5, and 6. Claim 1 is a generic claim. Claims 7-9 are withdrawn as being drawn to nonelected subject matter.

Claims 1-6 are pending.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 7/17/02 is acknowledged. A signed copy is enclosed hereto.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 3 and 6 provides for the use of, but, since the claims do not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for glycoproteins extracted from blood serum, liver, thymus or eye does not reasonably provide enablement for glycoproteins extracted from tissues taken from different organs of human beings and animals. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

In this regard, the application disclosure and claims have been compared per the factors indicated in the decision *In re Wands*, 8 USPQ2d 1400 (Fed. Cir., 1988) as to undue experimentation. The factors include:

1) the nature of the invention;
2) the breadth of the claims;
3) the predictability or unpredictability of the art
4) the amount of direction or guidance presented;
5) the presence or absence of working examples;
6) the quantity of experimentation necessary;
7) the state of the prior art; and,
8) the relative skill of those skilled in the art;

Each factor is addressed below on the basis of comparison of the disclosure, the claims

and the state of the prior art in the assessment of undue experimentation.

The claimed invention is drawn to glycoproteins extracted from blood serum, liver, thymus or eye.

The breadth of the claims is excessive with regard to claiming glycoproteins comprising any and all glycoproteins extracted from tissues taken from different organs of human beings and animals. Applicant has only provided guidance for the use of glycoproteins extracted from blood serum, liver, thymus or eye. Applicant have provided no guidance of any other glycoproteins extracted from tissues taken from different organs of human beings and animals. In absence of evidence to the contrary, it would not be expected that any and all glycoproteins extracted from tissues taken from different organs of human beings and animals would act as a medicinal agent . Furthermore, it would not be predictable to the artisan which glycoproteins extracted from tissues taken from different organs of human beings and animals would work in the present invention, nor would it be predictable to the artisan which pathologies could be treated with these glycoproteins.

In consideration of these factors, it is apparent that there is undue experimentation because of a variability in prediction of outcome that is not addressed by the present application. Absent factual data to the contrary, the amount and level of experimentation needed is undue to practice the invention as claimed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 3 and 6 are rejected because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example Ex parte Dunki, 153 USPQ 678 (Bd.App. 1967) and Clinical Products, Ltd v. Brenner, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

The intended metes and bounds of claims 1-6 cannot be determined by the plural term "glycoproteins" – e.g., which glycoproteins and how many? Please note that applicant is entitled to one invention per application. It is strongly suggested that the claims be amended so as to recite a singular glycoprotein (for example, -- A glycoprotein extracted... --) to overcome this rejection.

Claim 1 is rendered vague and indefinite by the phrase "extracted with the help of isoelectric focusing" (lines 1-2) because it is unclear by this ambiguous phrase if isoelectric focusing is or is not used to extract the claimed glycoprotein. It is suggested that this phrase be amended to recite -- extracted using isoelectric focusing --.

Claims 2 and 5 are grammatically awkward and confusing for reciting "Pharmaceutical composition, including...". It is suggested that this phrase be amended to recite -- A pharmaceutical composition comprising --.

Claims 2 –6 recite the limitation "glycoprotein" .There is insufficient antecedent basis for this limitation in the claim. It is suggested that this be amended to -- the glycoprotein – to correspond to the suggested claim language discussed supra for claim 1.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-6 are rejected under 35 U.S.C. 102(b)/ 103(a) as being anticipated/ unpatentable over Karler et al. (USPN 4,169,139).

The claimed invention is drawn to glycoproteins taken from different organs of human beings and animals, that are soluble in a saturated solution of ammonium sulfate, having an apparent molecular weight of 10-45 kDa and having biological activity in ultra low doses from 10(-12) to 10(-29) mol/liter and lower.

Karler teaches glyco/proteinaceous derivatives – i.e., mucoprotides comprised of proteins and carbohydrates (thus, glycoproteins) which appear to be identical to the presently claimed glycoproteins since they were also obtained from various mammalian organs (such as liver, placenta, spleen, kidney, pancreas, pituitary glands) and also demonstrate biological activity (see, e.g., for example, abstract, column 1-3, and column 11, claim 1). Consequently, the claimed glycoproteins appear to be anticipated by the reference.

In the alternative, even if the claimed glycoproteins are not identical to the referenced glycoproteins (i.e., mucoprotides) with regard to some unidentified characteristics, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced glycoproteins (e.g., molecular weights thereof), particularly in view of the similar characteristics which they have been shown to share. Thus, the claimed glycoproteins would have been obvious to those of ordinary skill in the art within the meaning of USC 103. If necessary, the result-effective adjustment in conventional working parameters (e.g., glycoproteins having biological activity in ultra low doses from 10(-12) to 10(-29) mol/liter and lower)- i.e., the adjustment of particular conventional working conditions is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Accordingly, the claimed invention as a whole was at least *prima facie* obvious, if not anticipated by the reference, especially in the absence of sufficient, clear, and convincing evidence to the contrary.

With respect to the above art rejection, please note that the Patent and trademark Office is not equipped to conduct experimentation in order to determine whether the apparent

molecular weight range of applicants' glycoproteins differ and, if so, to what extent, from those disclosed by the cited reference. Therefore, with the showing of the reference, the burden of establishing non-obviousness by objective evidence is shifted to the applicants.

Conclusion

All claims are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy Teller whose telephone number is 571-272-0971. The examiner can normally be reached on Monday-Friday from 5:30 am to 2:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Conclusion

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PRIMARY EXAMINER